

**REMARKS**

The present application has been amended to reflect the 371 status. In addition, the multiple dependencies of the claims have been eliminated to reduce the PTO filing fee.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached pages are captioned "**Version with markings to show changes made**".

Favorable action on the merits is solicited.

Respectfully submitted,

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butyl 2-hydroxyethylmalonate.

5. The process according to claim 1, wherein the cyclic ester compound is a cyclic monoester compound or a cyclic diester compound.

5 6. The process according to claim 1, wherein the deprotecting reaction is an acidolysis reaction.

7. A process for producing a biodegradable polymer having a free carboxyl group at the  $\omega$ -end comprising:

10 subjecting a cyclic ester compound to a polymerization reaction in the presence of a hydroxymonocarboxylic acid derivative in which the carboxyl group is protected, and

subjecting the resulting polymer having a protected carboxyl group at the  $\omega$ -end to a deprotecting reaction.

15 8. The process according to claim 7, wherein an acid hydrolysis reaction is carried out following the deprotecting reaction.

9. <sup>(Amended)</sup> The process according to claim 1 ~~or 7~~, wherein the biodegradable polymer is a biodegradable polymer that is used in a sustained-release preparation that releases a physiologically active substance over the course of at least about six months.

20 10. <sup>(Amended)</sup> A biodegradable polymer obtained by the production process as set forth in claim 1 ~~or 7~~.

25 11. A sustained-release preparation containing the biodegradable polymer as set forth in claim 10.

PROCESS FOR PRODUCING POLYMER

*This application is a 371 of PCT/JP99/07013 Filed December 14, 1999.*

Technical Field

5           The present invention relates to a process for producing a novel biodegradable polymer.

Background Art

10           EP-A-0839525 discloses a sustained-release preparation composed of a physiologically active peptide or its salt and a biodegradable polymer, and its production process, and the biodegradable polymer described in the publication is produced by subjecting a biodegradable polymer produced by a known ring-opening polymerization process to a  
15           hydrolysis process which itself is known.

          The ring-opening polymerization process uses a cyclic dimer of lactic acid by adding a catalyst while heating, and this process is described by J.H.R. Woodland et al. in the Journal of Medicinal Chemistry (J. Med. Chem.), Vol. 16,  
20           page 897 (1973). In addition, a process in which this is performed using a catalyst from a cyclic diester compound such as a lactide or glycolide is described in the Encyclopedic Handbook of Biomaterials and Bioengineering Part A: Materials, Vol. 2, Marcel Dekker, Inc. (1995).

25           Further, a process of producing a block copolymer in